

§ 600.12 Records.

(a) *Maintenance of records.* Records shall be made, concurrently with the performance, of each step in the manufacture and distribution of products, in such a manner that at any time successive steps in the manufacture and distribution of any lot may be traced by an inspector. Such records shall be legible and indelible, shall identify the person immediately responsible, shall include dates of the various steps, and be as detailed as necessary for clear understanding of each step by one experienced in the manufacture of products.

(b) *Records retention*—(1) *General.* Records shall be retained for such interval beyond the expiration date as is necessary for the individual product, to permit the return of any clinical report of unfavorable reactions. The retention period shall be no less than five years after the records of manufacture have been completed or six months after the latest expiration date for the individual product, whichever represents a later date.

(2) *Records of recall.* Complete records shall be maintained pertaining to the recall from distribution of any product upon notification by the Director, Center for Biologics Evaluation and Research, to recall for failure to conform with the standards prescribed in the regulations of this subchapter, because of deterioration of the product or for any other factor by reason of which the distribution of the product would constitute a danger to health.

(3) *Suspension of requirement for retention.* The Director, Center for Biologics Evaluation and Research, may authorize the suspension of the requirement to retain records of a specific manufacturing step upon a showing that such records no longer have significance for the purposes for which they were made: *Provided,* That a summary of such records shall be retained.

(c) *Records of sterilization of equipment and supplies.* Records relating to the mode of sterilization, date, duration, temperature and other conditions relating to each sterilization of equipment and supplies used in the processing of products shall be made by means of automatic recording devices or by means of a system of recording which gives equivalent assurance of the

accuracy and reliability of the record. Such records shall be maintained in a manner that permits an identification of the product with the particular manufacturing process to which the sterilization relates.

(d) *Animal necropsy records.* A necropsy record shall be kept on each animal from which a biological product has been obtained and which dies or is sacrificed while being so used.

(e) *Records in case of divided manufacturing responsibility.* If two or more establishments participate in the manufacture of a product, the records of each such establishment must show plainly the degree of its responsibility. In addition, each participating manufacturer shall furnish to the manufacturer who prepares the product in final form for sale, barter or exchange, a copy of all records relating to the manufacturing operations performed by such participating manufacturer insofar as they concern the safety, purity and potency of the lots of the product involved, and the manufacturer who prepares the product in final form shall retain a complete record of all the manufacturing operations relating to the product.

[38 FR 32048, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

§ 600.13 Retention samples.

Manufacturers shall retain for a period of at least 6 months after the expiration date, unless a different time period is specified in additional standards, a quantity of representative material of each lot of each product, sufficient for examination and testing for safety and potency, except Whole Blood, Cryoprecipitated AHF, Platelets, Red Blood Cells, Plasma, and Source Plasma and Allergenic Products prepared to a physician's prescription. Samples so retained shall be selected at random from either final container material, or from bulk and final containers, provided they include at least one final container as a final package, or package-equivalent of such filling of each lot of the product as intended for distribution. Such sample material shall be stored at temperatures and under conditions which will maintain

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the identity and integrity of the product. Samples retained as required in this section shall be in addition to samples of specific products required to be submitted to the Center for Biologics Evaluation and Research. Exceptions may be authorized by the Director, Center for Biologics Evaluation and Research, when the lot yields relatively few final containers and when such lots are prepared by the same method in large number and in close succession.

[41 FR 10428, Mar. 11, 1976, as amended at 49 FR 23833, June 8, 1984; 50 FR 4133, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990]

§ 600.14 Reporting of errors.

(a) The Director, Office of Compliance, Center for Biologics Evaluation and Research (HFB-100), 8800 Rockville Pike, Bethesda, MD 20892, shall be notified promptly of errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any product.

(b) Manufacturers of licensed in vitro diagnostic products, and manufacturers of unlicensed in vitro diagnostic products which are required to be registered under part 607 of this chapter, shall notify the Director in accordance with paragraph (a) of this section. Manufacturers of other in vitro diagnostic products which are required to be registered under part 807 of this chapter, shall report in accordance with part 803 of this chapter.

[38 FR 32048, Nov. 20, 1973, as amended at 49 FR 23833, June 8, 1984; 49 FR 36348, Sept. 14, 1984; 55 FR 11014, Mar. 26, 1990]

§ 600.15 Temperatures during shipment.

The following products shall be maintained during shipment at the specified temperatures:

(a) Products.

Product	Temperature
Cryoprecipitated AHF	– 18 °C or colder.
Measles and Rubella Virus Vaccine Live.	10 °C or colder.
Measles Live and Smallpox Vaccine.	Do.
Measles, Mumps, and Rubella Virus Vaccine Live.	Do.
Measles and Mumps Virus Vaccine Live.	Do.
Measles Virus Vaccine Live ..	Do.
Mumps Virus Vaccine Live	Do.

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Product	Temperature
Fresh Frozen Plasma	– 18 °C or colder.
Liquid Plasma	1 to 10 °C.
Plasma	– 18 °C or colder.
Platelet Rich Plasma	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 and 24 °C, if the label indicates storage between 20 and 24 °C.
Platelets	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 and 24 °C, if the label indicates storage between 20 and 24 °C.
Poliovirus Vaccine Live Oral Trivalent.	0 °C or colder.
Poliovirus Vaccine Live Oral Type I.	Do.
Poliovirus Vaccine Live Oral Type II.	Do.
Poliovirus Vaccine Live Oral Type III.	Do.
Red Blood Cells (liquid product).	Between 1 and 10 °C.
Red Blood Cells Frozen	– 65 °C or colder.
Rubella and Mumps Virus Vaccine Live.	10 °C or colder.
Rubella Virus Vaccine Live ...	Do.
Smallpox Vaccine (Liquid Product).	0 °C or colder.
Source Plasma	– 5 °C or colder.
Source Plasma Liquid	10 °C or colder.
Whole Blood	Blood that is transported from the collecting facility to the processing facility shall be transported in an environment capable of continuously cooling the blood toward a temperature range of 1 to 10 °C, or at a temperature as close as possible to 20 to 24 °C for a period not to exceed 6 hours. Blood transported from the storage facility shall be placed in an appropriate environment to maintain a temperature range between 1 to 10 °C during shipment.
Yellow Fever Vaccine	0 °C or colder.